

REMARKSI. Claim Status:

Upon entry of this Amendment, claims 1, 3-5, 7-29 and 52-62 will be pending. Claims 2, 6 and 30-35 have been cancelled. Claims 36-51 have been withdrawn and the election to prosecute the invention of group 1 is hereby affirmed.

Support for the amendment to claim 1 with respect to the specific anti-microbial agent and phospholipids used may be found in the specification at paragraphs 0032 thru 0045. Claim 7 has been amended by deleting the Markush group and selecting a specific phospholipid contained within that group. Support for the amendments to claims 8-11 with respect to the narrowing of the term anti-microbial agent to iodine can be found in the specification at paragraphs 0028 thru 0030. Support for new claim 52 can be found in the specification at paragraphs 0001 thru 0003 and 0007. Support for new claims 53-62 can be found in the specification at paragraphs 0032 thru 0043.

II. Amendments to the Specification:

Paragraph [0009] has been amended to better summarize independent claim 1 as amended herein. Support for this amendment can be found in the specification at paragraphs 32-43.

Paragraph [0023] has been amended to correct an obvious clerical error in the chemical structure Formula I. The new Formula I shows the correct chemical structure of cis-9, trans-11-octadecanamidopropyl phosphatidylglycerol.

Paragraphs [0024] - [0026] have been deleted because they describe an alternative embodiment incorrectly.

Paragraph [0027] has been amended to eliminate reference to the deleted paragraphs 0024-0026.

Paragraphs [0045] - [0046] have been amended replacing the term iodophor with iodine. Support for this amendment can be found at paragraphs 0045-0046 of the specification.

The objections to the informalities noted regarding trademarks have been addressed in the amendments to paragraphs [0074]-[0077] and [0080]-[0081].

### **III. §112 1st Paragraph Rejection of Claims 1-29**

Reconsideration is requested of the rejection of claims 1-29 under 35 U.S.C. §112, first paragraph. The Examiner has stated that the specification, while enabling for certain conditions, does not provide enablement for a composition for the treatment or prevention of any infection in any and all animals.

In response, claim 1 as amended is limited to a topical veterinary composition for the treatment or prevention of **bovine mammary infections**, and more specifically in new dependent claim 52, to the treatment or prevention of mastitis. Applicants therefore request withdrawal of the §112, first paragraph rejection.

With regard to claims 2 - 29, claims 2 and 6 have been cancelled, and claims 3-5 and 7-29 depend either directly or indirectly from claim 1, and are therefore patentable for the same reasons as claim 1. In addition, new claims 52-62 also depend directly from claim 1 and are therefore patentable for the same reasons as claim 1.

### **IV. §112 2nd Paragraph Rejection of Claims 6 and 31**

Reconsideration is requested of the rejection of claims 6 and 31 as being indefinite. Claims 6 and 31 have been cancelled, so this rejection is moot.

V. §102(b) RejectionsA. Beerse et al (6,258,368)

Reconsideration is requested of the rejection of claims 1 and 3 under 35 U.S.C. §102(b) as being anticipated by Beerse (U.S. Pat. No. 6,258,368).

Claim 1 as amended requires iodine as an antimicrobial agent and one of the following eleven specific phospholipids (all of which are phosphobetaines i.e., synthetic phospholipids):

linoleamidopropyl phosphatidylglycerol dimonium chloride phosphate;  
cocoamidopropyl phosphatidylglycerol dimonium chloride phosphate;  
sunfloweramidopropyl phosphatidylglycerol dimonium chloride phosphate;  
sodium olivamidopropyl phosphatidylglycerol dimonium chloride phosphate;  
stearamidopropyl phosphatidylglycerol dimonium chloride phosphate;  
ricinoleamidopropyl phosphatidylglycerol dimonium chloride phosphate;  
di-linoleamidopropyl phosphatidylglycerol dimonium chloride phosphate;  
poly(ethylene glycol)<sub>n=8</sub> dimethicone sunfloweramidopropyl phosphatidylglycerol dimonium chloride phosphate complex;  
dimethicone saffloweramidopropyl phosphatidylglycerol dimonium chloride phosphate complex;  
sodium grapeseedamidopropyl phosphatidylglycerol dimonium chloride phosphate; and  
sodium borageamidopropyl phosphatidylglycerol dimonium chloride phosphate.

In contrast to claim 1, Beerse discloses antimicrobial wipes comprising the following **essential** components:

a porous or absorbent sheet;  
an antimicrobial active;  
an anionic surfactant; and  
a proton donating agent.

In addition, Beerse discloses a mildness enhancer as an optional ingredient. One example of a mildness enhancer disclosed by Beerse is a lipophilic skin conditioning agent selected from the group comprising phospholipids and mixtures thereof.

As stated in MPEP 2131:

A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (emphasis added).

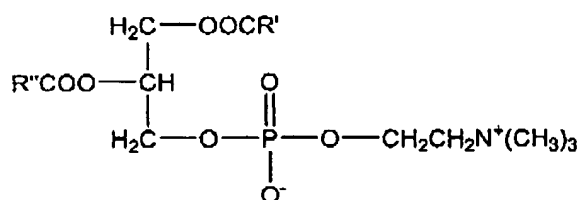
Inasmuch as Beerse fails to disclose or suggest incorporation of iodine as an antimicrobial agent, claim 1 is patentable.

Claim 1 is also patentable because Beerse fails to disclose or suggest any of the eleven specific phospholipids required in claim 1.

Accordingly, claim 1 is patentable because Beerse fails to disclose or suggest either of the foregoing express requirements.

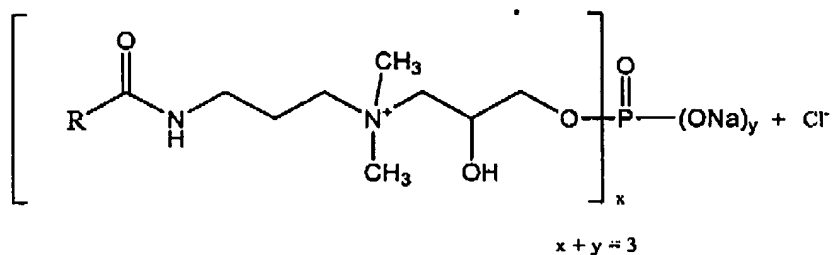
In addition, while claim 1 is patentable for the foregoing reasons, it is also worth noting that the respective classes of phospholipids are fundamentally different.

Phospholipids are generally defined as compounds formed from four components: fatty acids, a negatively charged phosphate group, an alcohol, and a backbone. Natural phospholipids are phospholipids with a glycerol backbone and are also known as glycerophospholipids or phosphoglycerides. One example of a natural phospholipid is phosphatidyl choline, also known as lecithin (see structure A). Another class of phospholipids consist of betaine derivatives and is discussed by Lindemann et. al. in U.S. 4,215,064. These phospholipids are classified as phosphobetaines and are commonly termed synthetic phospholipids (see structure B).



Phosphatidylcholine (phosphoglyceride)

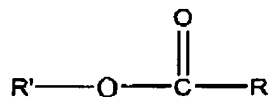
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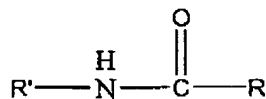
Phosphobetaine Phospholipid

B

Natural phospholipids (phosphoglycerides) are **esters** containing the functional group:



Contrastingly, synthetic phospholipids (phosphobetaines) are **amides** containing the functional group:



The phospholipids disclosed by Beerse (column 14, lines 64-67 and column 15, lines 1-67) are all phosphoglycerides or natural phospholipids. Contrastingly, claim 1 as amended, specifically requires one of the eleven specific phospholipids cited above, all of which are phosphobetaines, i.e., synthetic phospholipids. As shown above, the chemical structure of natural phospholipids (phosphoglycerides) is significantly different from that of synthetic phospholipids (phosphobetaines).

Accordingly, the types of phospholipids suggested by Beerse are fundamentally distinct from the species of phospholipids required in claim 1.

With regard to claim 3, it depends directly from claim 1, and is therefore patentable over Beerse for the same reasons as claim 1.

**B. Khan et al (5,824,359)**

Reconsideration is requested of the rejection of claims 1-4, 17, and 28-30 under 35 U.S.C. §102(b) as being anticipated by Khan (U.S. Pat. No. 5,824,359).

Claim 1 as amended requires iodine as an antimicrobial agent and one of the eleven specific phospholipids cited above.

In contrast to claim 1, Khan discloses a lubricant comprising lecithin and an antimicrobial agent. Lecithin, also known as phosphatidylcholine, is a natural phospholipid (glycerophospholipid or phosphoglyceride).

As stated in MPEP 2131:

A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (emphasis added).

Inasmuch as Khan fails to disclose or suggest a composition comprising iodine as an antimicrobial agent and any of the eleven specific phospholipids required in claim 1, claim 1 is patentable.

Claims 2 and 30 have been cancelled, so this rejection is moot. With regard to claims 3-4, 17, and 28-29, these claims all depend directly or indirectly from claim 1, and are therefore patentable over Khan for the same reasons as claim 1.

C. Jampani et al (WO 01/41727)

Reconsideration is requested of the rejection of claims 1, 3, 7, 17, 24, and 28-29 under 35 U.S.C. §102(b) as being anticipated by Jampani (WO 01/41727).

Claim 1 as amended requires iodine as an antimicrobial agent and one of the eleven specific phospholipids cited above.

In contrast to claim 1, Jampani discloses compositions comprising hydrophilic oil skin conditioners and an antimicrobial agent selected from the group consisting of benzalkonium chloride, benzethonium chloride, methyl benzethonium chloride, cetylpyridinium chloride, cetrimonium chloride, cetrimonium bromide (cetrimide), Cosmocil CQ (20% polyhexamethylene biguanide (PHMB)), and chlorhexidine gluconate.

As stated in MPEP 2131:

A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (emphasis added).

Inasmuch as Jampani fails to disclose or suggest incorporation of iodine as an antimicrobial agent, claim 1 is patentable.

With regard to claims 3, 7, 17, 24, and 28-29, these claims all depend directly or indirectly from claim 1, and are therefore patentable over Jampani for the same reasons as claim 1.

#### VI. §102(e) Rejections

##### A. Mayne et al(6,881,427)

Reconsideration is requested of the rejection of claims 1, 17, 24, and 28 under 35 U.S.C. §102(e) as being anticipated by Mayne (U.S. Pat. No. 6,881,427).

Claim 1 as amended requires iodine as an antimicrobial agent and one of the eleven specific phospholipids cited above.

In contrast to claim 1, Mayne discloses topical anti-inflammatory compositions comprising effective amounts of a linseed extract and a licorice extract. Additionally, Mayne discloses that its compositions may also contain various known and conventional cosmetic ingredients such as carriers, diluents, emollients, emulsifiers, surfactants, thickening agents, vitamins, skin conditioners, moisturizers, phospholipids, and anti-microbial agents.

As stated in MPEP 2131:

A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (emphasis added).

Inasmuch as Mayne fails to disclose or suggest incorporation of iodine as an antimicrobial agent, claim 1 is patentable.



Claim 1 is also patentable because Mayne fails to disclose or suggest any of the eleven specific phospholipids required in claim 1.

Accordingly, claim 1 is patentable because Mayne fails to disclose or suggest either of the foregoing express requirements.

With regard to claims 3, 7, 17, 24, and 28-29, these claims all depend directly or indirectly from claim 1, and are therefore patentable over Mayne for the same reasons as claim 1.

**B. Hei et al (6,436,445)**

Reconsideration is requested of the rejection of claims 1, 2, 30, and 32-35 under 35 U.S.C. §102(e) as being anticipated by Hei (U.S. Pat. No. 6,436,445).

Claim 1 as amended requires iodine as an antimicrobial agent and one of the eleven specific phospholipids cited above.

In contrast to claim 1, Hei discloses compositions comprising lecithin, mineral oil, iodine, and water. As stated above, lecithin is also known as phosphatidyl-choline which is a natural phospholipid (glycerophospholipid or phosphoglyceride).

As stated in MPEP 2131:

A claim is anticipated only if **each and every element** as set forth in the claim is found, either expressly or inherently described, in a single prior art reference (emphasis added).

Inasmuch as Hei fails to disclose or suggest any of the eleven specific phospholipids required in claim 1, claim 1 is patentable.

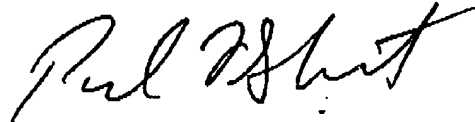
With regard to claims 2, 30 and 32-35, these claims have been cancelled and thus the rejection is moot.

VII. CONCLUSION

In view of the foregoing, applicants respectfully request issuance of a Notice of Allowance for claims 1, 3-5, 7-29 and 52-62.

The Commissioner is hereby authorized to charge the one-month extension fee for Amendment B in the amount of \$60.00 to Deposit Account No. 19-1345. The Commissioner is hereby authorized to charge any additional fees which may be required to Deposit Account No. 19-1345.

Respectfully submitted,



Paul I. J. Fleischut, Reg. No. 35,513  
SENNIGER POWERS  
One Metropolitan Square, 16th Floor  
St. Louis, Missouri 63102  
(314) 231-5400

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VIA FACSIMILE